

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 15, 1997 list were made in June, 1997

New Approvals

ANADA Number: 200-190

Pioneer Product: 091-191
Trade Name : Gentoral
Ingredients: Gentamicin sulfate
Sponsor: Med-Pharmex, Inc.
Approval Date: 05/27/97
Status: Over-the-counter
Route: Oral
Species: Porcine
Drug Form: Liquid (solution)
Concentration: 50 mg/mL
Indications: For the control and treatment of colibacillosis in weanling swine caused by strains of *E. coli* sensitive to gentamicin, and for the control and treatment of swine dysentery associated with *Treponema hyodysenteriae*.
Tolerance: 21CFR 556.300: 0.1 ppm in muscle, 0.3 ppm in liver, and 0.4 ppm in fat and kidney.
Withdrawal: 3days

21CFR 520.10441

NADA Number: 141-079

Trade Name : Ivomec Eprinex™ Pour-On for Beef and Dairy Cattle
Ingredients: Eprinomectin
Sponsor: Merck Research Laboratories
Approval Date: 04/16/97
Status: Over-the-counter
Route: Topical
Species: Bovine (beef and dairy cattle, including lactating dairy cattle and veal calves)
Drug Form: Liquid (solution)
Concentration: 5 mg/mL
Indications: For the treatment and control of the following species of gastrointestinal roundworms, lungworms, grubs, flies, lice and mange mites in cattle:
Gastrointestinal nematodes (adults and 4th stage larvae): *Haemonchus placei*, *Ostertagia ostertagi* (including inhibited L₄), *Trichostrongylus axei*, *Trichostrongylus colubriformis*, *Cooperia oncophora*, *Cooperia punctata*, *Cooperia surnabada*, *Nematodirus helvetianus*, *Bunostomum phlebotomum*, *Oesophagostomum radiatum*, *Trichuris* spp. (adults).
Lungworms (adults and 4th stage larvae): *Dictyocaulus viviparus*.
Cattle Grubs (all parasitic stages): *Hypoderma bovis*, *Hypoderma lineatum*.
Lice: *Damalinia bovis*, *Linognathus vituli*, *Haematopinus eurysternus*, *Solenopotes capillatus*.
Mange mites: *Chorioptes bovis*, *Sarcoptes scabiei*.
Flies: *Haematobia irritans*.
Tolerance: 21CFR 556.227: 12 ppb and 4.8 ppm for the B_{1a} component of eprinomectin (the marker residue) in milk and liver (the target tissues), respectively.
Withdrawal: Zero milk discard and zero tissue withdrawal.
Patent Number: 4,427,663 Expiration date: 03/16/2002
5,602,107 05/10/2013
Exclusivity: 5 years

21CFR 524.814

Actions Taken by FDA Center for Veterinary Medicine

NADA Number: 141-080

Trade Name : Anipryl
Ingredients: Selegiline hydrochloride
Sponsor: Deprenyl Animal Health
Approval Date: 05/30/97
Status: Prescription only
Route: Oral
Species: Canine
Drug Form: Tablets
Concentration: 2 mg, 5, mg, 10 mg, 15 mg, and 30 mg/tablet
Indications: For the control of clinical signs associated with uncomplicated pituitary-dependent hyperadrenocorticism (PDH).
Patent Number: 5,225,446 Expiration date: 08/31/2010
 5,276,057 01/04/2011
 5,387,615 02/07/2012
 5,565,495 10/15/2013
 5,561,163 10/01/2013
 5,151,449 08/31/2010
 5,192,808 08/31/2010
Exclusivity: 5 years

21CFR 510.600 & 520.2098

Change of Sponsor

The following NADAs were transferred from Fermenta Animal Health Co. to Boehringer Ingelheim Animal Health, Inc, 2621 North Belt Hwy., St. Joseph, MO 65406; drug labeler code 000010:

011-531	049-032	117-689	136-212
011-674	065-178	125-797	137-310
012-469	065-486	126-236	137-694
031-512	065-491	126-676	138-869
033-803	065-496	127-034	138-955
035-918	092-837	127-627	139-472
038-200	097-452	128-069	140-270
039-077	098-569	129-034	140-442
040-848	106-772	131-538	140-916
043-606	108-963	132-028	141-011
045-143	109-305	134-644	200-023
048-237	117-531	134-708	200-029
048-271	117-532	135-771	200-165

Addition of New Sponsor

Deprenyl Animal Health, Inc.,
7101 College Blvd., Suite 580,
Overland Park, KS 66210
Drug labeler code: 063248